UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/660,785 | 09/12/2003 | Joern Moeckel | 2924-216 | 5867 |

6449 7590 05/29/2008

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

| EXAMINER | |
|---|---|
| SILVERMAN, ERIC E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1618 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 05/29/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/660,785 | MOECKEL ET AL. | |
| | Examiner | Art Unit | |
| | Eric E. Silverman, PhD | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21-35 and 37-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-35 and 37-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicants' response, filed 3/24/2008 has bee received. Claims 21 – 35 and 37 – 43 are pending in this action, claims 42 and 43 being newly added in the abovementioned response.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 – 35 and 37 – 41 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **The new matter rejection is maintained for reasons of record and those discussed below**.

### *Response to Arguments*

Applicants' arguments have been fully considered, but are not persuasive. Applicants argue that page 7 of the specification discloses the use of pore formers with gastric-juice resistant films. Applicants note that while this section does not provide verbatim support for the claims, verbatim support is not required.

In response, the section of the specification cited by Applicants has been closely scrutinized. This section provides that specific polymers specified therein may be used along with a pore former or in a "very thin layer thickness". However, this section does

not provide support for the combination of any of the polymers of instant claims along wit a pore former "when a coating [polymer] is used which does not dissolve during contact with the digestive solution in a patient's stomach", as claimed.

It is noted that claim 42, which only uses a pore former with those polymers specifically listed in the specification as useable with a pore former, is *not* included in this rejection.

Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

Claim 43 is drawn to a coating of hydroxypropyl methylcellulose phthalate and lactose. The original disclosure does not envision this specific combination. In Example 4 in the specification, hydroxypropyl methylcellulose phthalate (there called methyl hydroxypropyl cellulose phthalate) is used, but there is no lactose. Nowhere in the original disclosure is the combination of hydroxypropyl methylcellulose phthalate and lactose discussed, nor does Applicants' response point to the location in the disclosure that is believed to support the new claim.

Claims 21 – 35 and 37 – 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use

the invention. **This enablement rejection is maintained for reasons of record and those discussed below**.

*1. The new claims*

Claim 42 is similar to claim 21 except that a smaller genus of polymer coatings is required to be used with a pore former. However, all of the coatings of claim 42 are enteric, and for reasons explained in the previous office action, would not be expected to release a drug in the stomach. As explained in the previous office action, enteric polymers are used to release drugs in the intestine, and to avoid release in the stomach. Claim 43 is directed to a specific embodiment of claim 42 which also uses an enteric polymer.

*2. Response to Arguments*

Applicant argues that the use of pore formers in polymer coatings is well known in the art, and that the artisan would be able to determine the appropriate type and amount of pore former to provide a release of greater than 30% of the drug into the stomach.

In response, it is first noted that Applicants' arguments are not to be mistaken for evidence of record. With that in mind, the Examiner is not aware, nor does Applicants' response point to, any evidence of record that supports the notion that combinations of enteric polymers and pore formers were well known in the art at the time of the invention. To the extent that such combinations were well known, the Examiner is not aware, nor has Applicant pointed out, evidence of record indication that such

combinations can predictably provide delivery to the stomach of at least 30% of a drug from an oral dosage form.

Applicants' note that "[t]he present invention lies in the discovery that bond disease can be treated with ibandorate which is in an oral formulation and which is released in a patient's stomach." 3/24/20 response, page 13. The instant claims limit the coating to specific polymers. Applicants never actually teach how to obtain the claimed effect (delivery into the stomach), which Applicants' believe to make the claims novel and unobvious (see generally the response filed 8/30/2005) with the claimed polymers. Instead, Applicants believe that it the artisan could readily determine how to obtain this effect, using only that which is allegedly well known in the art.

However, the evidence that is of record indicates that a person of skill in the art would expect an enteric coating to release drugs not in the stomach but in the intestine. Indeed, Applicants appear to have admitted this to be the case. See Applicants' response filed 8/30/2005 at 9, 10 ("[E]nteric coatings release the drug in the intestine not the stomach.") The evidence that is of record also indicates that all of the polymers of the instant claims are enteric polymers. Because enteric polymers release drug in the intestine, not the stomach and the instantly claimed polymers are enteric polymers, it follows that the instantly claimed polymers would be expected to release the drug in the intestine, not in the stomach. As there is no evidence of record to contradict this expectation, the rejection must be maintained.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Eric E. Silverman, PhD
Art Unit 1618